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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,258	07/30/2003	Arthur G. Taveras	OC01406K5	9404
24265	7590	11/23/2005	EXAMINER	
SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			FREISTEIN, ANDREW B	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/630,258	Applicant(s) TAVERAS ET AL.	
	Examiner Andrew B. Freistein	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-157 is/are pending in the application.
- 4a) Of the above claim(s) 104-157 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9, 10, 15-18, 22-27, 37-57 and 96-99 is/are rejected.
- 7) ☒ Claim(s) 1-103 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/12/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Claims 1-157 are currently pending in the instant application.

***Priority***

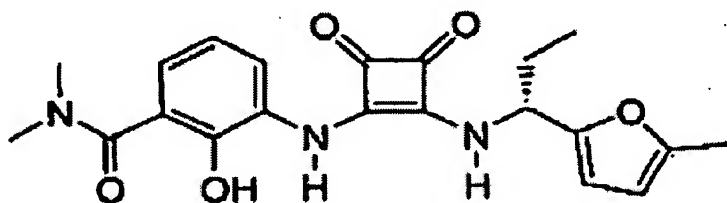
This application is a Continuation In Part of US Application Serial No. 10/241,326, filed 09/11/2002, which was abandoned, which in turn is a Continuation In Part of US Application Serial No. 10/208,412, filed 07/30/2002, which was abandoned, which in turn is a Continuation In Part of US Application Serial No. 10/122,841, filed 04/15/2002, which was abandoned, which in turn claims benefit of US Provisional Pat. Application No. 60/284,026, filed 04/16/2001.

***Information Disclosure Statement***

Applicants' information disclosure statement (IDS), filed on 4/12/2004, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

***Response to Restriction Requirement***

Acknowledgement is made of Applicants' election (with traverse) of Group I, Claims 1-103, drawn to products of Formula (IA), and the species,



, in a response filed 10/11/2005.

The Examiner respectfully disagrees with the Applicants' traversal because the products of Inventions I and II differ materially in structure and element and from each other and are therefore capable of supporting their own patents. The invention groups I and II are related to a set of structurally diverse compounds and their methods of use.

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Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The chemical structures claimed do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Due to the plethora of classes and subclasses in each of group, separate search considerations are involved, which would impose a serious burden on the Examiner.

Nevertheless, Examiner may reconsider to rejoin the method of use claims commensurate in scope with the product claims when and if the case is found to be in condition for allowance provided those method of use claims are free of 35 U.S.C. § 112 first and second paragraph issues (including written description, reach-through claim language and/or scope of enablement issues).

Applicants reserve their right to file a divisional application on the non-elected subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

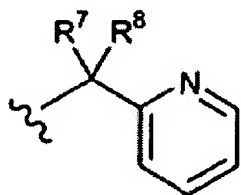
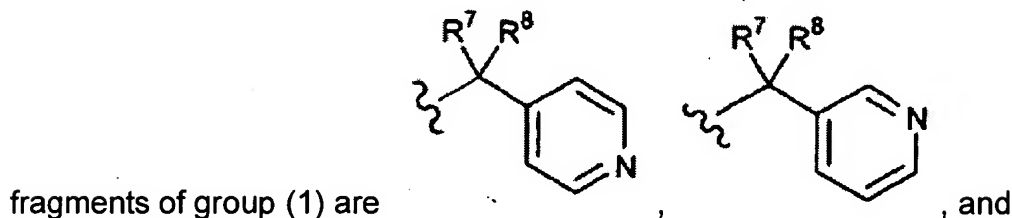
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1 is rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

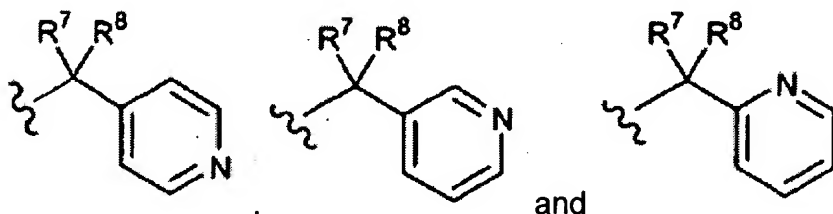
In claim 1 the definition of variable, "A" is selected from the group consisting of a group (1), (2), (3), (4) and (5), wherein different fragments are drawn. Many of the

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fragments overlap each other in the different groups. For example, the first three



Similarly, the first three fragments of group (2) are



The definition of the variable A should be single alternatives rather than overlapping alternatives. Claim 1 should be amended to delete the specific groups (1)-(5) and simply list all of the possible fragments in one large group without any repeats. Alternatively, each fragment can be numbered separately, similar to the way variable "B" is currently defined.

**Claims 96-99 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 96-99 claim a compound selected from examples, but does not show the species claimed. Examiner presumes the claim is directed to the examples in the

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specification. However, this is improper. The Applicant must particularly point out and distinctly *claim* the invention. The Applicant must identify the invention with the appropriate chemical structure and/or the specific chemical name in the claim itself rather than referring to the specification with an example number.

### ***Claim Rejections – Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

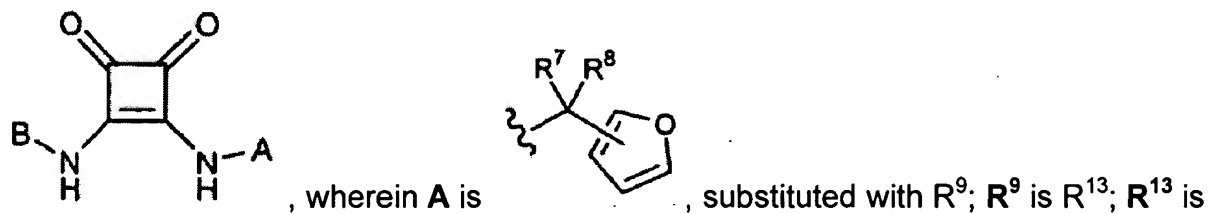
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

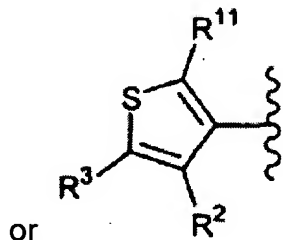
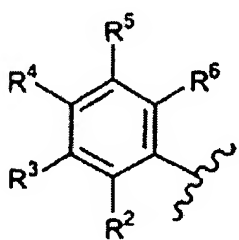
**Claims 1-4, 6, 7, 9, 10, 15-18, 22-27 and 37-57** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 58, 59, 60, and 62 of Copending U.S. Pat. Application No. 10/390,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

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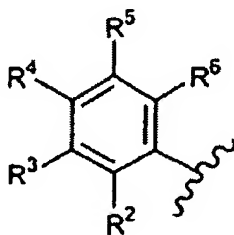
Applicants claim 3,4-Di-substituted cyclobutene-1,2-diones as CXC-chemokine receptor ligands. Claim 1 of the instant application claims a compound of formula (IA),



H, substituted or unsubstituted alkyl, or substituted or unsubstituted heteroaryl; R<sup>7</sup> and R<sup>8</sup> are each independently H or substituted or unsubstituted alkyl; B is

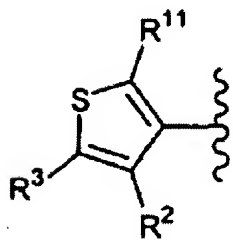


or ; R<sup>4</sup>, R<sup>5</sup>, R<sup>6</sup>, and R<sup>11</sup> are each H; R<sup>2</sup> is OH



; R<sup>3</sup> is C(O)NR<sup>13</sup>R<sup>14</sup> when B is

and SO<sub>(t)</sub>NR<sup>13</sup>R<sup>14</sup> when B is

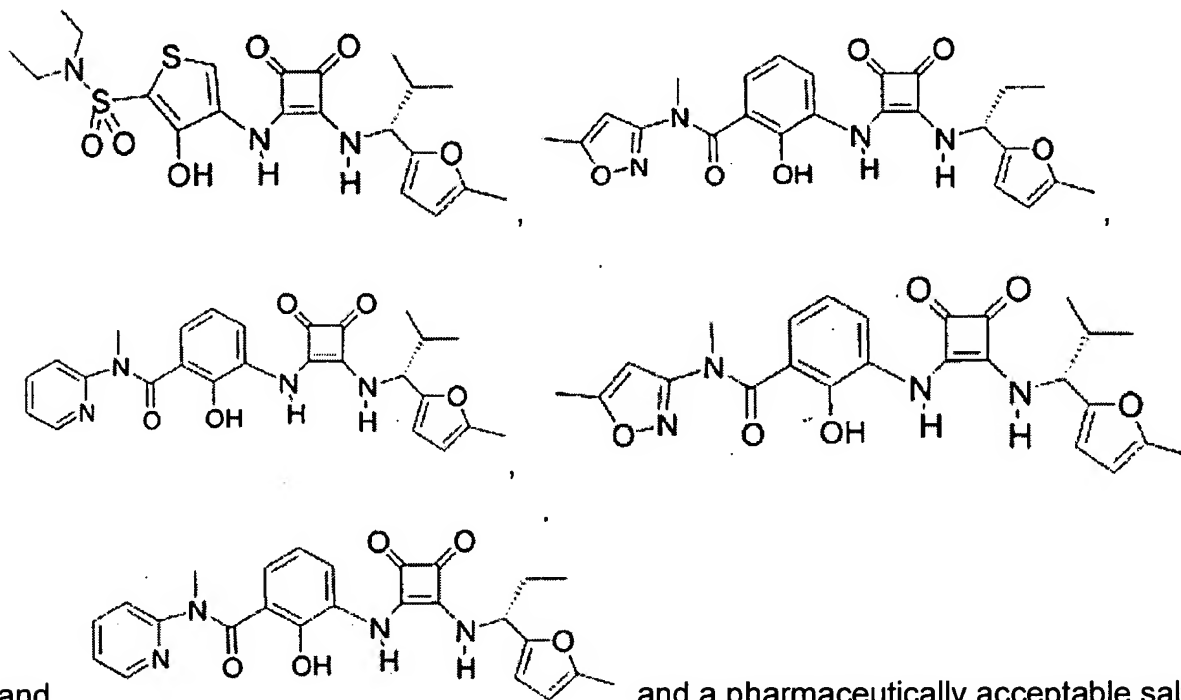


; R<sup>14</sup> is H, substituted or unsubstituted alkyl, or substituted or

unsubstituted heteroaryl; and t is 2; and pharmaceutically acceptable salts and solvates thereof.

Determining the Scope and Content of the Copending Application

Claims 58, 62, 63 and 64 of the copending application claim the three species:



and

, and a pharmaceutically acceptable salt or solvate thereof.

Ascertaining the Differences Between the Instant Application and the Copending Application

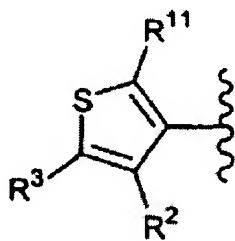
The instant application is not limited the definitions shown above. Rather, the instant application claims many different variables for "A" and "B" of formula (IA).

The species identified in the copending application are very specific species. The copending application contains mostly method of treating CXC chemokine mediated diseases. There are only a few chemical compounds claimed. Nevertheless, all of the species of the copending application read on formula (IA) as defined in claim 1 of the instant application.



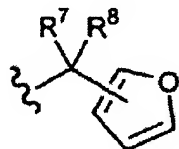
*Finding Prima Facie Obviousness*

The species claimed in the copending application read on formula (Ia) of the instant application. Many of the dependent claims of the instant application claims variations of formula (Ia) wherein they are similar to the species claimed in the copending application. For example, claims 16-27 of the instant application each have



the variable B as and claims 23-27 each claim R<sup>3</sup> to be SO<sub>(t)</sub>NR<sup>13</sup>R<sup>14</sup>.

Similarly, claims 32-36 each claim compounds of Formula (Ia) wherein A is



The species of the copending application fit into these dependent claims of the instant application. Therefore, one of ordinary skill in the art would be motivated to produce the species of the copending application with the disclosure of the instant application. As a result, the claims are provisionally rejected under the obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Status of the Claims***

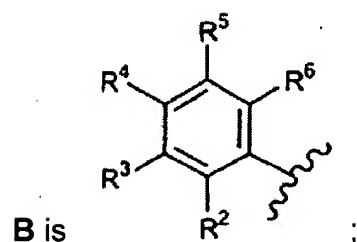
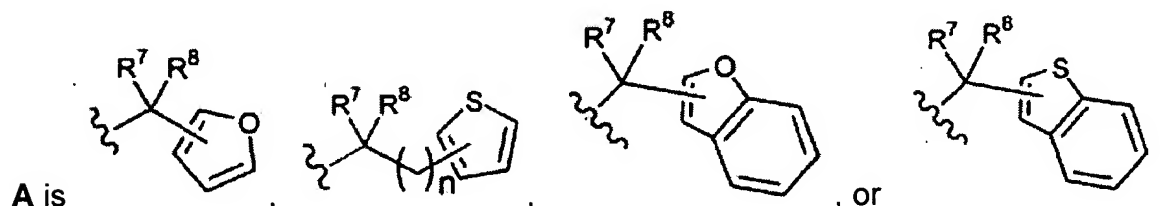
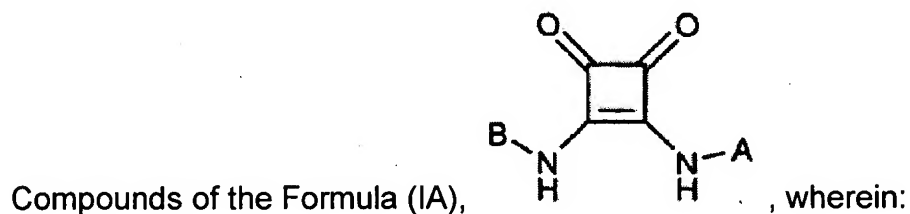
Claims 1-103 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn

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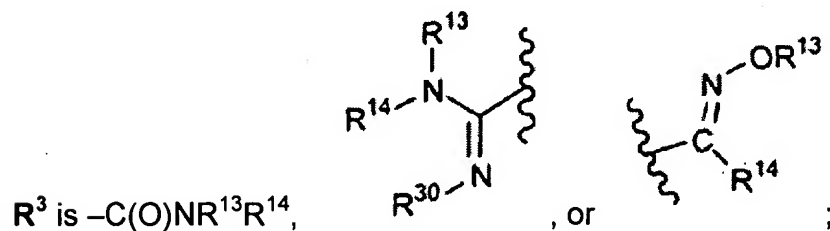
subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

### Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



$R^2$  is hydrogen, OH,  $C(O)OH$ , SH,  $SO_2NR^{13}R^{14}$ ,  $NHC(O)R^{13}$ ,  $NHSO_2R^{13}R^{14}$ ,  $NHSO_2R^{13}$ ,  $NR^{13}R^{14}$ ,  $C(O)NR^{13}R^{14}$ ,  $C(O)NHOR^{13}$ ,  $C(O)NR^{13}OH$ ,  $S(O_2)OH$ , or  $OC(O)R^{13}$ ;



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$R^4$  is H, cyano, halogen, alkyl, alkoxy, OH,  $CF_3$ ,  $OCF_3$ ,  $NO_2$ ,  $C(O)R^{13}$ ,  $C(O)OR^{13}$ ,  $C(O)NHR^{17}$ ,  $C(O)NHR^{13}R^{14}$ ,  $SO_{(t)}NR^{13}R^{14}$ ,  $SO_{(t)}R^{13}$ , or  $C(O)NR^{13}OR^{14}$ , or unsubstituted aryl;

$R^5$  is H, halogen, alkyl, alkoxy, OH,  $CF_3$ ,  $OCF_3$ ,  $NO_2$ ,  $C(O)R^{13}$ ,  $C(O)OR^{13}$ ,  $C(O)NHR^{13}R^{14}$ ,  $SO_{(t)}NR^{13}R^{14}$ , or  $C(O)NR^{13}OR^{14}$ , cyano, or unsubstituted aryl;

$R^6$  is H, halogen, alkyl, alkoxy, OH,  $CF_3$ ,  $OCF_3$ ,  $NO_2$ ,  $C(O)R^{13}$ ,  $C(O)OR^{13}$ ,  $C(O)NHR^{13}R^{14}$ ,  $SO_{(t)}NR^{13}R^{14}$ , or  $C(O)NR^{13}OR^{14}$ , cyano, or unsubstituted aryl;

$R^7$  is H, alkyl, alkenyl, alkynyl, or cycloalkyl, each substituted with halogen,  $CF_3$ ,  $COR^{13}$ ,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $NO_2$ , CN,  $SO_2OR^{13}$ ,  $CO_2R^{13}$ ,  $C(O)R^{13}$ ,  $C(O)NR^{13}R^{14}$ ,  $NR^{13}C(O)R^{14}$ , or  $NR^{13}CO_2R^{14}$ ;

$R^8$  is H, alkyl, alkenyl, alkynyl, or cycloalkyl, each substituted with halogen,  $CF_3$ ,  $COR^{13}$ ,  $OR^{13}$ ,  $NR^{13}R^{14}$ ,  $NO_2$ , CN,  $SO_2OR^{13}$ ,  $CO_2R^{13}$ ,  $C(O)R^{13}$ ,  $C(O)NR^{13}R^{14}$ ,  $NR^{13}C(O)R^{14}$ , or  $NR^{13}CO_2R^{14}$ ;

$R^9$  is  $R^{13}$ ;

$R^{13}$  is H or unsubstituted alkyl;

$R^{14}$  is H or unsubstituted alkyl;

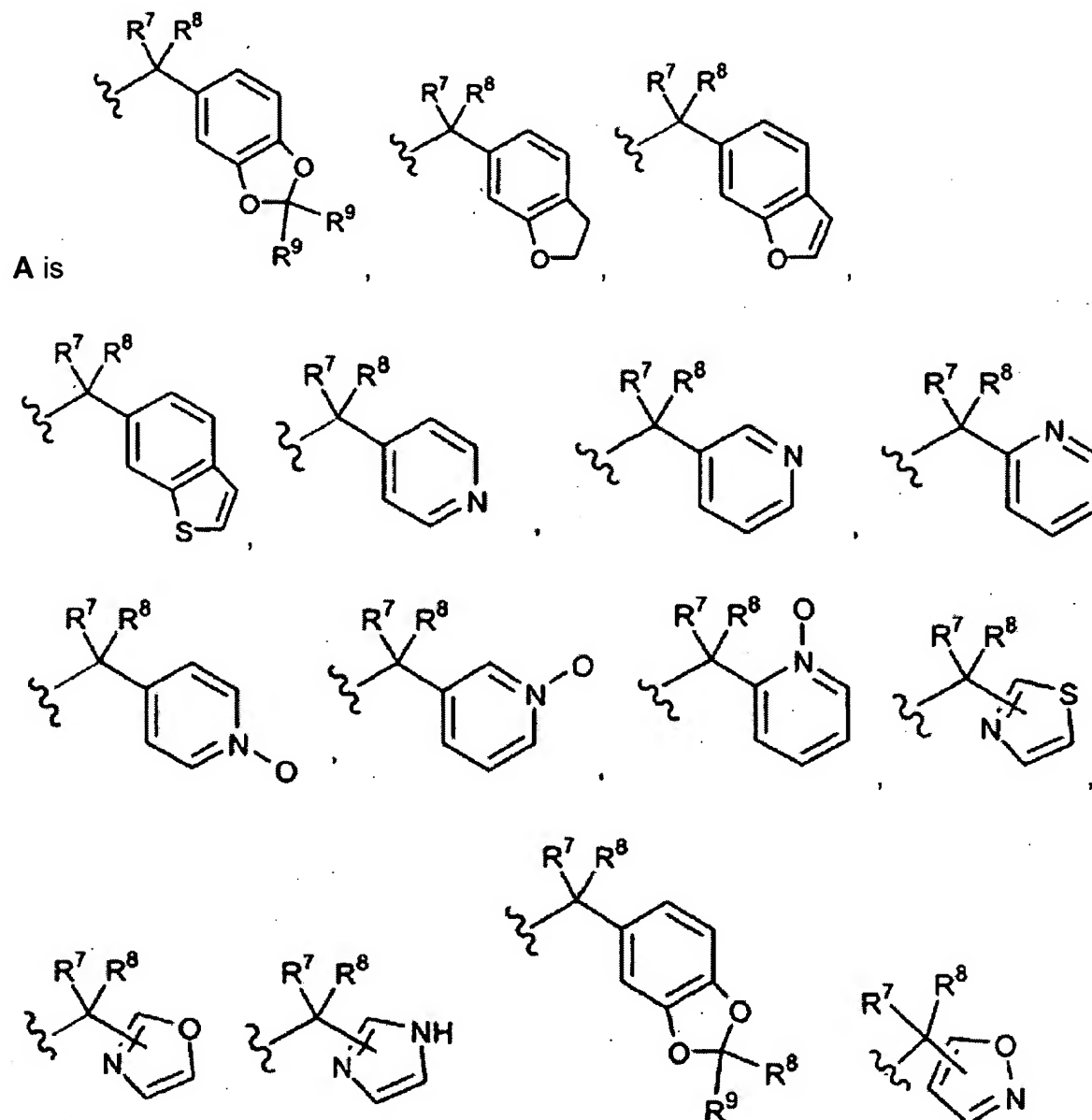
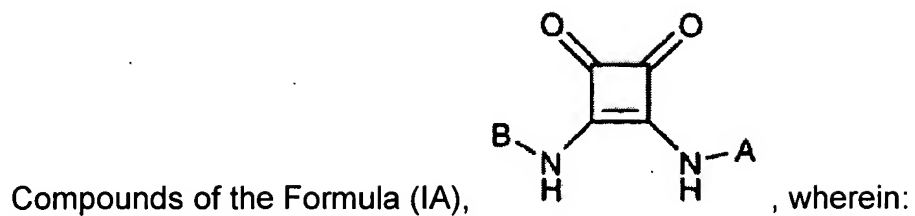
$n$  is 0; and

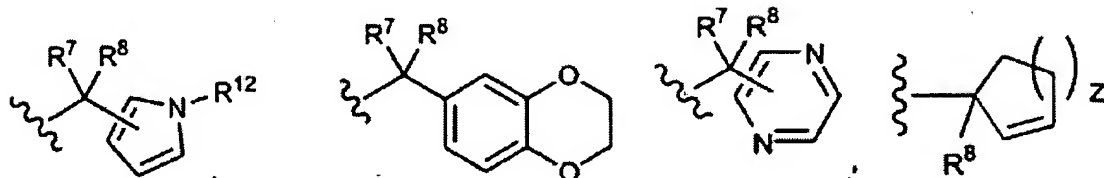
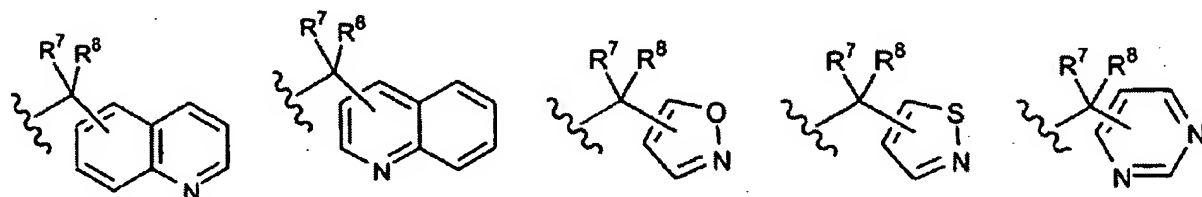
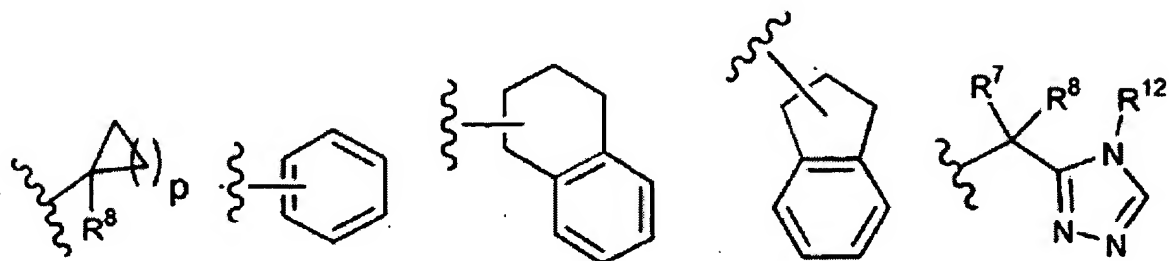
$t$  is 0, 1, or 2;

#### Non-elected and Non-examined Subject Matter

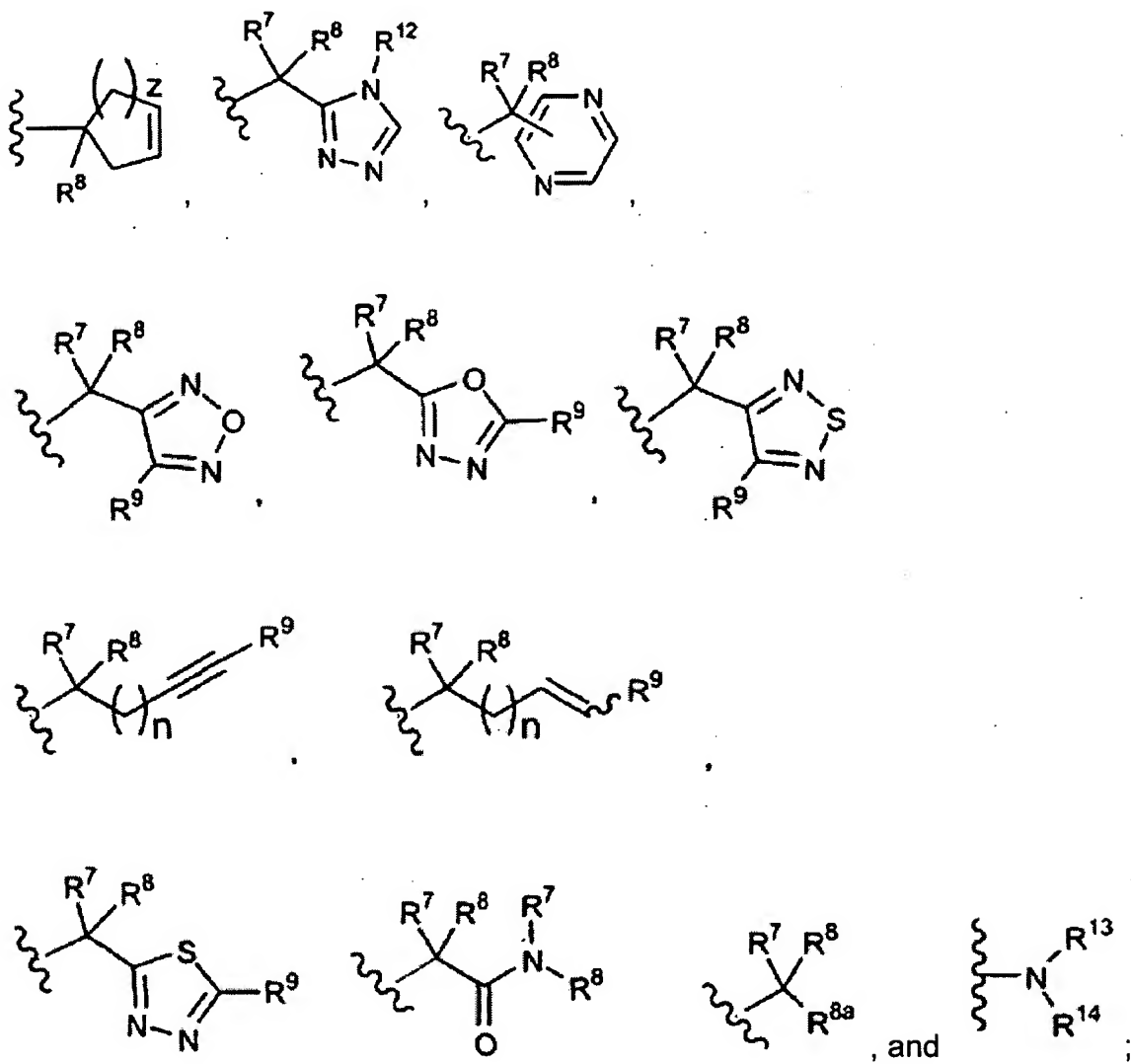
The scope of the invention of the non-elected and non-examined subject matter is as follows:

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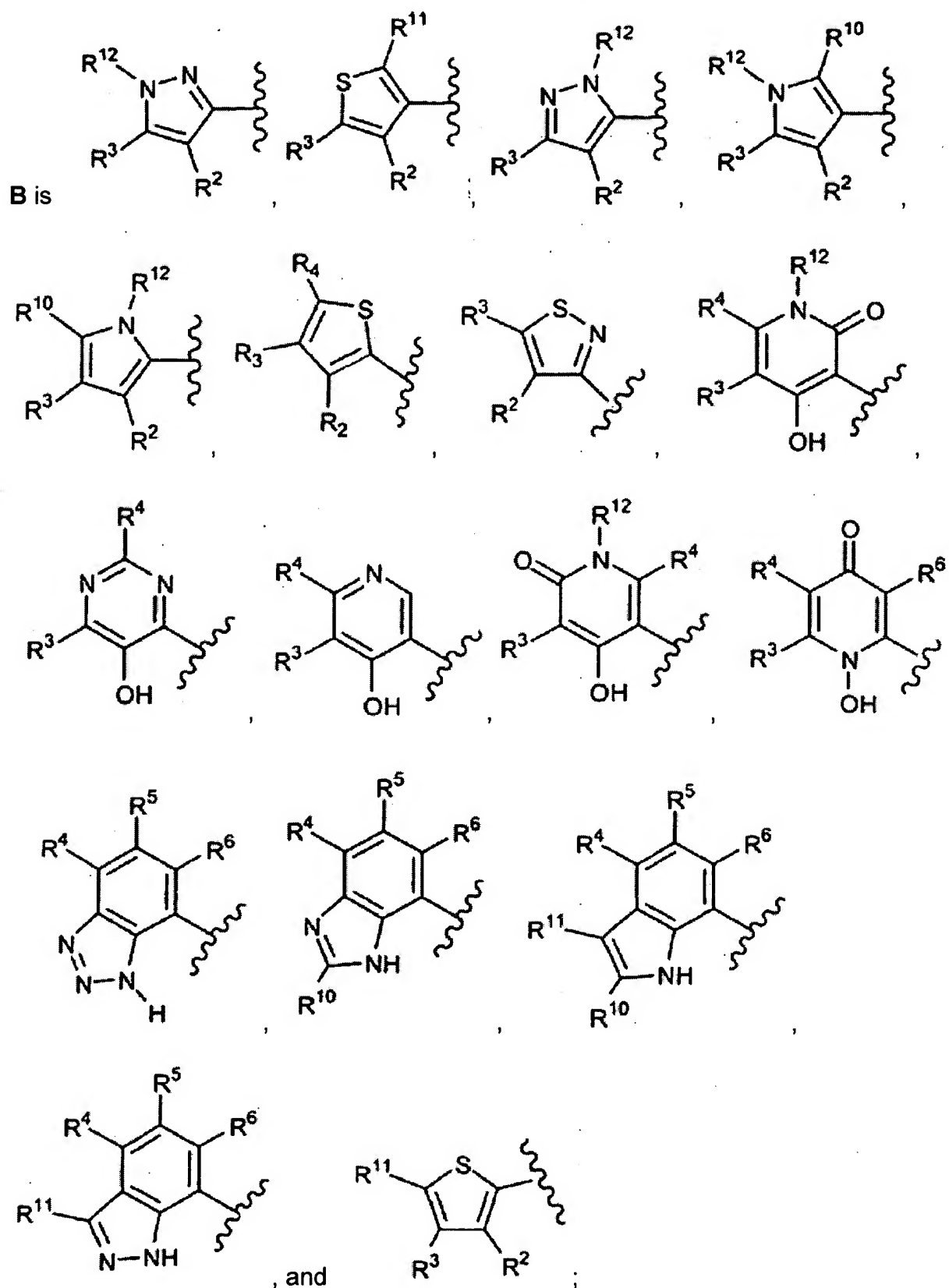




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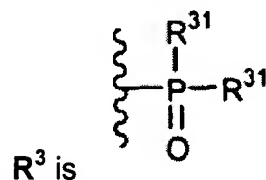


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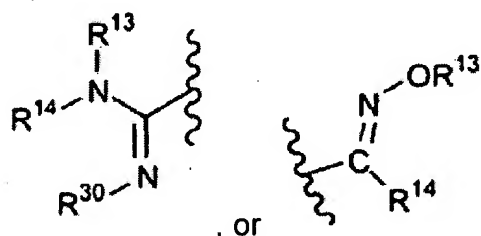
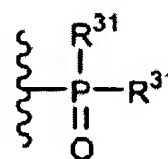


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$R^2$  is an unsubstituted heterocyclic acidic functional group, and a substituted heterocyclic acidic functional group, substituted as defined in claim 1;



$R^4$  is substituted aryl, substituted or unsubstituted heteroaryl,



$R^5$  is substituted aryl or substituted or unsubstituted heteroaryl;

$R^6$  is substituted aryl or substituted or unsubstituted heteroaryl;

$R^7$  is heteroaryl, heteroarylalkyl,  $\text{CO}_2R_{13}$ ,  $\text{CONR}_{13}R_{14}$ , each optionally substituted with  $\text{Si}(\text{alkyl})_3$ ,  $\text{Si}(\text{aryl})_3$ , or  $(R^{13})_2R^{14}\text{Si}$ ;

$R^8$  is heteroaryl, heteroarylalkyl,  $\text{CO}_2R_{13}$ ,  $\text{CONR}_{13}R_{14}$ , each optionally substituted with  $\text{Si}(\text{alkyl})_3$ ,  $\text{Si}(\text{aryl})_3$ , or  $(R^{13})_2R^{14}\text{Si}$ ;

$R^9$  is as defined in claim 1 other than  $R^{13}$ ;

$R^{13}$  is as defined in claim 1 other than H and unsubstituted alkyl;

$R^{14}$  is as defined in claim 1 other than H and unsubstituted alkyl;

$n$  is 1 to 6; and



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x is as defined in claim 1.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 1-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as piperazine, piperadine, pyrazole, pyrrolidine, dioxane, thiazole, oxazole, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

### ***Claim Objections***

Claims 1-3, 6, 15, 16-29, 37, 58, 59-65, 68-71, 73-76, 78-81, 86, 87, and 93-99 are objected to as being drawn to non-elected subject matter.

Claims 2-103 are objected to as being dependent upon a rejected base claim.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

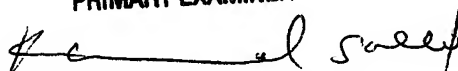
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER



Kamal Saeed, Ph.D.  
Primary Patent Examiner, AU 1626  
Date: November 21, 2005